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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/767,633	01/23/2001	Judith L. Treadway	PC10721ATMC	3428

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EXAMINER
CHISM, BILLY D

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 07/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/767,633	TREADWAY, JUDITH L.	
	Examiner	Art Unit	
	B. Dell Chism	1654	

-- Th MAILING DATE of this communication appears on the cover she t with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

This Office Action is in response to Paper No. 5, filed 07 April 2003. The Examiner has considered the Applicant's traversal of the restriction requirement and the requirement has been withdrawn. Claims 1-11 are pending and under consideration as originally filed.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment of diabetic cardiomyopathy, does not reasonably provide enablement for prevention of injury to the myocardium or prevention of the onset of diabetic cardiomyopathy, or how to make and use the prodrug and salts thereof, or for the use of the prodrugs and/or salts thereof in conjunction with additional compounds including the analogs, antagonists and agonists of the claimed additional compounds. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The specification does not give any guidance as to the full range of myocardium injuries that could be treated or prevented using the instant claimed process or guidance regarding prevention of the onset of diabetic cardiomyopathy, or how to make and use the prodrug and salts thereof, or for the use of the prodrugs and/or salts thereof in conjunction with additional compounds including the analogs, antagonists and agonists of the claimed additional compounds. In In re Wands, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a

disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

1. the nature of the invention: Applicants are claiming a method of preventing or treating myocardium injury and preventing onset of diabetic cardiomyopathy by administering any glycogen phosphorylase inhibitor and prodrugs and/or salts thereof, and treating with the claimed compounds and an additional compound along with the analogs, agonists and antagonists of the additional compounds.

2. the state of the prior art and the predictability or lack thereof in the art: The state of the prior art is that the art teaches use of the compounds for treatment of diabetic cardiomyopathy through in vitro methods, however, there is no evidence of predictability of the compounds for in vivo use of the compounds or the prodrugs or salts thereof, and no teachings of predictability for use of the compounds with additional compounds and their analogs, agonists and antagonists. The nature of the pharmaceutical arts is that it involves screening in vitro and in vivo to determine which compounds exhibit the desired pharmacological activities, i.e., prevention. However, there is no prior art that teaches predictability of the compounds with their prodrugs and/or salts thereof with additional compounds and/or the analogs, agonists or antagonists thereof for in vivo use.

There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face regarding prevention of all myocardium injury or the prevention of the onset of diabetic

cardiomyopathy through the use of one of the claimed compounds or prodrugs and/or salts thereof with an additional compound and/or the analogs, agonists and antagonists thereof.

4. the amount of direction or guidance present and presence of working examples: The instant specification does not give any guidance as to the full range of myocardium injuries that could be prevented using the instant claimed process, nor does it give guidance as how to prevent the onset of diabetic cardiomyopathy. Furthermore, there are no working examples in the specification that would lead one skilled in the art to understand the use, i.e., therapeutic application, of a compound for the prevention of myocardium injury or the prodrugs and/or salts thereof, with an additional compound and/or agonists, antagonists or analogs thereof.

5. the level of the skill in the art: In order to practice the claimed invention, one skilled in the art would have to speculate which claimed compound or prodrug or prodrug salt to be used with an additional compound and/or analog, agonist and/or antagonist thereof, should be used to treat which diabetic complicating disease and how to use it in vivo.

6. the quantity of experimentation needed: To prevent the number of possible myocardium injuries embraced by the claims, i.e., a puncture wound, and to do so by deciding what combination of compounds with additional compounds, agonists, antagonists or analogs and what routes of administration in vivo would impose undue experimentation on the skilled art worker.

7. the breadth of the claims: Therefore, the broad terminology "prevention of injury to the myocardium" is not enabled because the metes and bounds of the injuries that could be treated or prevented using the claimed method in the instant claims cannot be ascertained. Additionally, "preventing...the onset of diabetic cardiomyopathy" with a claimed compound

prodrug and/or salt thereof, alone or with an additional compound and/or its agonists, antagonists and/or analogs thereof, also is not enabled.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 3 and 10-11 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 is rejected for the indefinite recitation of the phrase "but not having..." wherein it is not clear, according to syntax, what is encompassed by the claim. It is not clear if every recitation after the phrase "but not having..." is applied to cardiovascular disease or if it is just coronary arteriosclerosis that applies to the phrase.

Claim 10 is rejected for the indefinite recitation of "and" and "or" wherein it is improper Markush practice to mix the "and" and "or".

Claim 11 is rejected for the indefinite recitation of the acronym NHE, wherein the full word length representation should be spelled out for the first use and the acronym used thereinafter.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an

> international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1, 3-7, 9 and 11 are rejected under 35 U.S.C. 102(e) as being anticipated by either of US 6,294,538 B1 (Mylari) or US 6,277,877 B1 (Hoover *et al.*).

The applied references have a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

7. Claims 1, 3-7, 9 and 11 are rejected under 35 U.S.C. 102(e) as being anticipated by Mylari. Mylari teaches treatment of diabetic complications, including diabetic cardiomyopathy and injury to the myocardium, using glycogen phosphorylase inhibitor (GPI) (column 6 lines 20-42, abstract). Furthermore, Mylari teaches use of sorbitol dehydrogenase inhibitor with a GPI (see abstract).

8. Claims 1-8 are rejected under 35 U.S.C. 102(e) as being anticipated by Hoover *et al.* Hoover *et al.* teaches methods of treatment for injury to the myocardium using a GPI for patients "at risk" of diabetic cardiomyopathy. Under the principles of inherency, if a prior art method, in its normal operation, would necessarily perform the method claimed, then the method claimed will be considered as anticipated by the prior art method. (MPEP §2112.02).

The preceding rejection is based on the judicial precedent following *In re* Fitzgerald, 205 USPQ 594, because the prior art is silent with regard to the patients being "at risk" of diabetic cardiomyopathy.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being obvious over Hoover *et al.* (US 6,277,877 B1) in view of Mylari (US 6,294,538 B1).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or

subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Hoover *et al.* teach using compounds of claim 2 (specific GPIs) of present application for the treatment of diabetes and for the treatment of hypertension, however, Hoover *et al.* do not teach use of the compounds of claim 2 (specific GPIs) for treatment of patients having diabetic cardiomyopathy (column 34 lines 5-40).

Mylari teaches treatment of diabetic patients having diabetic cardiomyopathy using any GPI, however, Mylari does not teach the specific GPI compounds of claim 2 (column 6 lines 20-42, abstract).

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to use a GPI, known for treatment of diabetic cardiomyopathy, to treat diabetics with hypertension, especially since it was known at the time the invention was made that one of skill in the art could use GPI to treat diabetics and hypertension.

Conclusions

No claims allowed. Claim 10 is objected to for depending from rejected claim 9.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to B. Dell Chism whose telephone number is 703-306-5815. The examiner can normally be reached on 7:30 AM - 4:30 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 703-306-3220. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

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B. Dell Chism
19 June 2003

BRENDA BRUMBACK
SUPERVISORY PATENT EXAMINER
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